HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use NAMENDA XR capsules safely and effectively. See full prescribing information for NAMENDA XR capsules.

NAMENDA  $XR^\theta$  (memantine hydrochloride) extended-release capsules, for oral use Initial U.S. Approval: 2003

INDICATIONS AND USAGE

NAMENDA XR is a N-methyl-Daspartate (NMDA) receptor antagonist indicated for the treatment of moderate to severe dementia of the Alzbeimer's type, (1)

- tue of the Adhremer's type. (1)

  \*\*DOSAGE AND ADMINISTRATION\*\*

  \*\*DOSAGE ADMINISTRATION\*\*

  \*\*
- DOSAGE FORMS AND STRENGT IS
   NAMENDA XR is available as an extended-release capsule in the following strengths: 7 mg, 14 mg, 21 mg, 28 mg (3)
- CONTRAINDICATIONS

  NAMENDA XR is contraindicated in patients with known hypersensitivity to memantine hydrochloride or to any excipients used in the formulation. (4)
- WARNINGS AND PRECAUTIONS
   Conditions that raise urine pH may decrease the urinary elimination of memantine resulting in increased plasma levels of memantine. (5.1, 7.1)

ADVERSE REACTIONS

The most commonly observed adverse reactions occurring at a frequency of at least 5% and greater than placebo with administration of NAMENDA XR 28 mg/day were headache, distribute and dizziness. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1-800-678-1605 or FDA at 1-800-FDA-1088 or www.ifata.ovimedwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 11/2019

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# FULL PRESCRIBING INFORMATION

#### INDICATIONS AND USAGE

NAMENDA XR® is indicated for the treatment of moderate to severe dementia of the Alzheimer's

# 2 DOSAGE AND ADMINISTRATION

# 2.1 Recommended Dosing

The dosage of NAMENDA XR shown to be effective in a controlled clinical trial is 28 mg once daily. The congregor is Aramana Assimation for relicious material management with an impact 20 mg user camp. The recommended starting dose of NAMENDA XR is 7 mg once daily. The flower should be increased in 7 mg increments to the recommended instruments dose of 28 mg once daily. The minimum recommended interval between dose in creases is no new seek. The dose should only be increased if the previous dose has been well tolerated. The maximum recommended dose is 28 mg once daily.

NAMENDA XR can be taken with or without food. NAMENDA XR capsules can be taken intact or may be opened, sprinkled on applesauce, and thereby swallowed. The entire contents of each NAMENDA XR capsule should be consumed; the dose should not be divided.

XR Capaties should be consumed; the dose should not be divided, the NAMENDA XR should be swallowed and sprinided on applessauce, as described above, NAMENDA XR should be swallowed whole. NAMENDA XR capaties should not be divided, chewed, or crushed. If a patient misses a single dose of NAMENDA XR that patient should not double up on the next dose. The next dose should be taken as scheduled. If a patient fails to take NAMENDA XR for several days, dosing may need be be resumed at lower doses and retirated as described above.

# 2.2 Switching from NAMENDA to NAMENDA XR Capsules

Patients treated with NAMENDA may be switched to NAMENDA XR capsules as follows:

raterists tracted with INAMENDA may be switched to NAMENDA AR Capsures as forthows. It is recommended that a patient who is on a regimen of 10 mg wire daily of NAMENDA be switched to NAMENDA XR 28 mg once daily capsules the day following the last dose of 10 mg NAMENDA. There is no study addressing the comparative efficacy of these 2 regimens. In a patient with server renal impairment, it is recommended that a patient who is on a regimen of 5 mg twice daily of NAMENDA be switched to NAMENDA XR 14 mg once daily capsules the day following the last dose of 5 mg NAMENDA.

# 2.3 Dosing in Patients with Renal Impairment

Dosing in auteus was recent impainment.

In patients with severe renal impairment (creatinine clearance of 5 – 29 ml/min, based on the Cockroft-Gault equation), the recommended maintenance dose (and maximum recommended dose) is 14 mg/day [see cliquad long).

# 3 DOSAGE FORMS AND STRENGTHS

- 3 DUSAGE FURMS AND STRENGT HS
  Each capaule comists 7 mg. 14 mg. 21 mg, or 28 mg of memartine hydrochloride.

   The 7 mg capsules are a yellow opaque capsule, with "FLI 7 mg" black imprira.

   The 14 mg capsules are a yellow cap and dark green opaque body capsule, with "FLI 14 mg" black imprira on the yellow cap.

   The 21 mg capsules are a white to off-white cap and dark green opaque body capsule, with "FLI 21 mg" black imprira on the white to off-white cap.

   The 23 mg capsules are a what green opaque capsule, with "FLI 28 mg" white imprira.

# 4 CONTRAINDICATIONS

NAMENDA XR is contraindicated in patients with known hypersensitivity to memantine hydrochloride or to any excipients used in the formulation.

# 5.1 Genitourinary Conditions

Conditions that raise urine pH may decrease the urinary elimination of memantine resulting in increased plasma levels of memantine [see Drug Interactions (7.1)].

# 6 ADVERSE REACTIONS

# 6.1 Clinical Trials Experience

NAMENDA XR was evaluated in a double-blind placebo-controlled trial in which a total of 676 patients with moderate to severe dementia of the Alzbeimer's type (341 patients on NAMENDA XR 28 mg/day and 355 patients on placebo) were treated for up to 24 weeks.

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug camot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

# Adverse Reactions Leading to Discontinuation

In the placebo-controlled clinical trial of NAMENDA XR, the proportion of patients in the NAMENDA XR group and the placebo group who discontinued treatment due to adverse reactions was 10% and 6%, respectively. The most common adverse reaction that led to treatment discontinuation in the NAMENDA XR group was discreases, at a rate of 1.5%.

Most Common Adverse Reactions

The most commonly observed adverse reactions seen in patients administered NAMENDA XR in the controlled clinical trial, defined as those occurring at a frequency of at least 5% in the NAMENDA XR

group and at a frequency higher than placebo, were headache, diarrhea and dizzines

Table 1 lists adverse reactions that were observed at an incidence of ≥ 2% in the NAMENDA XR group and occurred at a rate greater than placebo.

Table 1: Adverse Reactions Observed with a Frequency of ≥ 2% in the NAMENDA XR Group and at a Rate Greater than Placebo

| Adverse Reaction                | Placebo<br>(n=335) | NAMENDA XR 28 mg<br>(n=341) |
|---------------------------------|--------------------|-----------------------------|
|                                 | %                  | %                           |
| Gas trointes tinal Disorders    |                    |                             |
| Diarrhea                        | 4                  | 5                           |
| Constipation                    | 1                  | 3                           |
| Abdominal pain                  | 1                  | 2                           |
| Vomiting                        | 1                  | 2                           |
| Infections and Infestations     |                    |                             |
| Influenza                       | 3                  | 4                           |
| Investigations                  |                    |                             |
| Weight, increased               | 1                  | 3                           |
| Musculos keletal and Connective |                    |                             |
| Tissue Disorders                |                    |                             |
| Back pain                       | 1                  | 3                           |
| Nervous System Disorders        |                    |                             |
| Headache                        | 5                  | 6                           |
| Dizziness                       | 1                  | 5                           |
| Somnolence                      | 1                  | 3                           |
| Psychiatric Disorders           |                    |                             |
| Anxiety                         | 3                  | 4                           |
| Depression                      | 1                  | 3                           |
| Aggression                      | 1                  | 2                           |
| Renal and Urinary Disorders     |                    |                             |
| Urinary incontinence            | 1                  | 2                           |
| Vascular Disorders              |                    |                             |
| Hypertension                    | 2                  | 4                           |
| Hypotension                     | 1                  | 2                           |

Memartine has not been systematically evaluated in patients with a seizure disorder. In clinical trials of memartine, seizures occurred in 0.3% of patients treated with memantine and 0.6% of patients treated with placebo.

The following adverse reactions have been identified during post-approval use of memantine

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These reactions include:

Blood and Lymphatic System Disorders: agranulocytosis, leukopenia (including neutropenia), pancytopenia, thrombocytopenia, thrombotic thrombocytopenic purpura. Cardiac Disorders: cardiac failure congestive.

Gastrointestinal Disorders: pancreatitis.

Hepatobiliary Disorders: hepatitis

Renal and Urinary Disorders: acute renal failure (including increased creatinine and renal insufficiency).

Skin Disorders: Stevens Johnson syndrome.

#### 7 DRUG INTERACTIONS

#### 7.1 Drugs That Make Urine Alkaline

The clearace of memaritie was reduced by about 80% under alkaline urine conditions at pH 8. Therefore, alterators of urine pH towards the alkaline condition may lead to an accumulation of the drug with a possible increase in adverse effects. Urine pH is altered by diet, drugs (e.g., carbonic analystraes inhibitors, sodium bit carbonate) and clinical state of the patier (e.g. renal tubular acidosis or severe infections of the urinary tract). Hence, memarine should be used with caution under these conditions.

7.2 Use with Other N-methyl-D-aspartate (NMDA) Antagonists
The combined use of NAMENDA XR with other NMDA antagonists (amartadine, ketamine, and dextromethorphan) has not been systematically evaluated and such use should be approached with caution.

#### 8 USE IN SPECIFIC POPULATIONS

#### Risk Summary

There are no adequate data on the developmental risk associated with the use of NAMENDA XR in pregnant women

Adverse developmental effects (decreased body weight and skeletal ossification) were observed in the offspring of rats administered memantine during pregnancy at doses associated with minimal maternal toxicity. These doses are higher than those used in humans at the maximum recommended daily dose of NAMENDA XR (see Da In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

#### Data

#### Animal Data

Contain Accusation of memartine (0, 2, 6, or 18 mg/kg/day) to rats during the period of organogenesis resulted in decreased skeletal ossification in fetuses at the highest dose tested. The higher noeffect dose for adverse developmental effects (6 mg/kg) is 2
times the maximum recommended human daily dose (MRHD) of NAMENDA XR (28
mg) on a body surface area (mg/m²) basis.

Oral administration of memantine to rabbits (0, 3, 10, or 30 mg/kg/day) during the period of organogenesis resulted in no adverse developmental effects. The highest dose tested is approximately 20 times the MRHD of NAMENDA XR on a mg/m<sup>2</sup> basis.

In ras, memanting (0, 2, 6, or 18 mg/kg/day) was administered or ally prior to and throughout muting and, in females, through the period of organogenesis or continuing throughout lacution to wearing. Decreased skeletal ossification in fetuses and decreased body weight in pups were observed at the highest dose tested. The higher notified toos for adverse developmental effect (5 mg/kg/day) is 2 times the MRHIO on an angiral basis.

Oral administration of memantine (0, 2, 6, or 18 mg/kg/day) to rats from late gestation throughout lactation to wearing, resulted in decreased pup weights at the highest dose tested. The higher no-effect dose (6 mg/kg/day) is approximately 2 times the MRHD of NAMENDA XR on a mg/m² basis.

# Risk Summary

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NAMENDA XR and any potential adverse effects on the breastfed infant from NAMENDA XR or from the underlying maternal condition.

# 8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Somey and executiveness improunding patterns in two not poern estimatished. Memarities falled to demonstrate efficacy into vol 2-week-controlled clinical studies of 578 pediatric patients aged 6-12 years with antism spectrum disorders (ASD), including autism, Asperger's disorder and Pervasive Development Disorder. Not Otherwise Specified (PDD-NOS), Memaritish inso to been studied in prediatric patients under 6 years of age or over 12 years of age. Memaritis retainent was offered from the control of the control

weights < 20 kg, 20-39 kg, 40-59 kg and ≥ 60 kg, respectively.

In a randomized, 12-week double-blind, placebo-controlled parallel study (Study A) in patients with anistin, there was no statistically significant difference in the Social Responsiveness Scale (SRS) total raw score between patients randomized to mematrine (n=54) and those randomized to placebo (n=53) in all 2-week responsive-reriched randomized withdrawal study (Study B) all 71 patients with ASD, there was no statistically significant difference in the loss of therapeutic response rates between patients randomized to remain on full-dose memantine (n=153) and those randomized to switch to placebo (n=158).

The overall safety profile of memantine in pediatric patients was generally consistent with the known safety profile in adults [see Adverse Reactions (6.1)].

In Study A, the adverse reactions in the memantine group (n=56) that were reported in at least 5% of patients and at least twice the frequency of the placebo group (N=58) are listed in Table 2.

# $\label{eq:Table 2: Study A Commonly Reported Adverse} Reactions with a Frequency $\geq 5\%$ and Twice That of Placebo$

| Adverse Reaction                                      | Memantine<br>N=56 | Placebo<br>N=58 |
|---|-------------------|-----------------|
| Cough   | 8.9%              | 3.4%            |
| Influenza   | 7.1%              | 3.4%            |
| Rhinorrhea  | 5.4%              | 0%              |
| Agitation   | 5.4%              | 1.7%            |
| Discontinuations                                      | due to Adverse Re | eactions a      |
| Aggression  | 3.6%              | 1.7%            |
| Irritability  | 1.8%              | 3.4%            |
| Reported adverse reacti<br>more than one patient in e |                   |                 |

The adverse reactions that were reported in at least 5% of patients in the 12-48 week open-label study to identify responders to enroll in Study B are listed in Table 3.

# Table 3: 12-48 Week Open Label Lead-In study to Study B Commonly Reported Adverse Reactions with a

pharyngitis

| Adverse Reaction | Memantine<br>N=903 |  |
|------------------|--------------------|--|
| Headache         | 8.0%               |  |

| Irritability   | 5.4%                     |  |  |  |
|--|--------------------------|--|--|--|
| Discontinuations due to Adverse Reactions <sup>a</sup> |                          |  |  |  |
| Irritability   | 1.2%                     |  |  |  |
| Aggression   | 1.0%                     |  |  |  |
| At least 1% incidence of adve                          | rse reactions leading to |  |  |  |

In the randomized withdrawal study (Study B), the adverse reaction in patients randomized to placebo (n=160) and reported in at least 5% of patients and twice that of the full-dose memantine treatment grout (n=157) was irribability (3.0% vs. 2.5%).

#### Juvenile Animal Study

In a juverile arisin study, mile and female juvenile rats were admiristered memarine (15, 30, and 45 mg/kg/day) starting on postnatal day (PND) 14 through PND 70. Body weights were reduced at 45 mg/kg/day) starting on postnatal day (PND) 14 through PND 70. Body weights were reduced at 45 mg/kg/day. Memaritine induced neuronal lesions in several areas of the Drain on PND 15 and 17 at doses ≥ 30 mg/kg/day. Memaritine induced neuronal lesions in several areas of the Drain on PND 15 and 17 at doses ≥ 30 mg/kg/day. Body on the 15 mg/kg/day dose and unforty startle habitation) was noted for animals in the 45 mg/kg/day dose group. The 15 mg/kg/day dose was considered the No-Observed-Adverse-Effect-Level (NOAEL) for this sub-

Effect-Level (NOAEL) for this study.

In a second juveralle rat toxicity study, male and female juveralle rats were administered menantine (1, 3, 8, 15, 30, and 45 mg/sg/day) sterning on postuntal day (PND)? through PND 70. Due to early menantine-related mortality, the 30 and 45 mg/sg/day dose groups were terminated without further produced to the state of the state

#### 8.5 Geriatric Use

8.5 Geriatric Use The majority of people with Alzheimer's disease are 65 years of age and older. In the clinical study of mematric hydrochloride extended-release, the mean age of patients was approximately 77 years; over 19% of patients were 65 years and older, 67% were 75 years and older, and 14% were at or above 85 years of age. The efficacy and safety data presented in the clinical trial sections were obtained from these patients. There were no clinically meaningful differences in most adverse reactions reported by patient groups 2.6 years old and <65 years old.</p>

#### 8.6 Renal Impairment

No dosage adjustment is needed in patients with mild or moderate renal impairment. A dosage reduction is recommended in patients with severe renal impairment [see Dosage and Administration (2.3) and Clinical Pharmacology (12.3)].

#### 8.7 Hepatic Impairment

No dosage adjustment is needed in patients with mild or moderate hepatic impairment. Namenda XR was not studied in patients with severe hepatic impairment [see Clinical Pharmacology (12.3)].

IV UVERDOSAGE
Sigm and symptoms most often accompanying overdosage with other formulations of memantine in clinical trials and from worldwide marketing experience, alone or in combination with other drugs and/or alcohol, include agitation, ashenia, bradycardia, confusion, com, dizziness, ECG changes, increased blood pressure, lethragy, loss of consciousness, psychosis, restlessness, slowed movement, somoelores, support, unsteady gait, visual hallucitations, vertigo, vomiting, and weakness. The largest with unspectified and indiabetic medications. This patient experienced come, diplopia, and agitation, but subsequently recovered.

One patient participating in a NAMENDA XR clinical trial unintentionally took 112 mg of NAMENDA XR daily for 31 days and experienced an elevated serum uric acid, elevated serum alkaline phosphatase and low platelet count.

Fatal outcome has been very rarely reported with memantine, and the relationship to memantine was

Because strategies for the management of overdose are continually evolving, it is advisable to contact a poison control center to determine the latest recommendations for the management of an overdose of any drug. As in any cases of overdose, general supportive measures should be utilized, and treatment should

Elimination of memantine can be enhanced by acidification of urine

#### 11 DESCRIPTION

NAMENDA XR (memantine hydrochloride) is an orally active NMDA receptor antagonist. The chemical name for memantine hydrochloride is 1-amino-3,5-dimethyladamantane hydrochloride with the following structural formula:



The molecular formula is  $C_{12}H_{21}N^{2}HC1$  and the molecular weight is 215.76. Memantine hydrochloride occurs as a fine white to off-white powder and is soluble in water.

NAMENDA XR capsules are supplied for oral administration as 7 mg, 14 mg, 21 mg, and 28 mg capsules. Each capsule contains extended-release beads with the labeled amount of memantine hydrochloride and the following inactive ingredients: sugar spheres, polyvinylpyrrolidore, hypromellose, talc, polyvelylere glycol, ethylicellulose, ammonium hydroxide, oleic acid, and medium chain triglycerdess in hard gelatin capsules.

# 12 CLINICAL PHARMACOLOGY

# 12.1 Mechanism of Action

ILLI Mechanism of Action

Persister activation of central nervous system N-methyl-D-aspartate (NMDA) receptors by the excitatory amino acid glutamate has been hypothesized to contribute to the symptomatology of Alzheimer's disease. Memartine is postulated to exert its therapeutic effect through its action as a low to moderate affinity uncompetitive (open-chame!) NMDA receptor antagonist which binds preferentially to the NMDA receptor-operated cation chamels. There is no evidence that memantine prevents or slows neurodegeneration in patients with Alzheimer's disease.

# 12.2 Pharmacodynamics

Memarine showed low to negligible affinity for GABA, beruodiazepine, dopamine, adrenergic, histamine and glycine receptors and for voltage-dependert Ga<sup>2</sup>/, Na<sup>2</sup>, or K<sup>2</sup> channels. Memartine also showed antagonistic effects at the SHT<sub>2</sub> receptor with a potexty similar to that for the NMDA receptor and blocked ricotinic acetylcholine receptors with one-sixth to one-tenth the potency.

In vitro studies have shown that memantine does not affect the reversible inhibition of acetylcholinesterase by donepezil, galantamine, or tacrine.

# 12.3 Pharmacokinetics

Memurine is well absorbed after oral administration and has linear pharmacokinetics over the therapeutic dose range. It is excreted predominarily unchanged in urine and has a terminal elimination half-life of about 0.68 ob hours. In a study comparing 28 mg once daily NAMENDA XR to 10 mg twice daily NAMENDA, the  $C_{\rm max}$  and  $AUC_{0.24}$  values were 48% and 33% higher for the XR dosage regime, respectively.

# Absorption

Absorption
Alter multiple dose administration of NAMENDA XR, memartine peak concentrations occur around 912 hours post-dose. There is no difference in the absorption of NAMENDA XR, when the capsule is alten intact or when the cortexts are sprindled on applessance.

There is no difference in memartine exposure, for a form of AUC, for NAMENDA XR whether that drug products administered with food or on an empty stomach. However, peak plasma concernations are achieved about 16 hours after administration with food dress as feer administration with food versus approximately 25 hours after administration with food trends and the state of th

The mean volume of distribution of memantine is 9-11 L/kg and the plasma protein binding is low (45%).

#### Elimination Metabolism

Memantine undergoes partial hepatic metabolism. The hepatic microsomal CYP450 enzyme system does not play a significant role in the metabolism of memantine.

Memarine is excreted predominantly unchanged in the urine and has a terminal elimination half-life of about 60-80 hours. About 48% of administered drug is excreted unchanged in urine; the remainder is converted primarily to three polar metabolites which possess minimal NMDA receptor attagolistic activity; the N-glucuronide conjugate, 6-hydroxy-memarine, and 1-airnoso-dearninand memarine. A total of 74% of the administered does is excreted as the sum of the parent drug and the N-glucuronide conjugate. Renal clearance involves active tubular secretion moderated by pH dependent tubular readsorption.

# Specific Populations

Elderly

The pharmacokinetics of memantine in young and elderly subjects are similar

Gender

Following multiple dose administration of memantine hydrochloride 20 mg daily, females had about 45% higher exposure than males, but there was no difference in exposure when body weight was taken

Renal Impairment

Renal Impairment
Memarize pharmacokinetics were evaluated following single oral administration of 20 mg memarize
hydrochloride in 8 subjects with mild renal impairment (creatinine clearance, CLCr., > 50 – 80 mL/min),
8 subjects with more are renal impairment (CLCx 30 – 94 mL/min), 7 subjects with sewere real
impairment (CLCx 5 – 29 mL/min) and 8 healthy subjects (CLCx > 80 mL/min) matched as closely as
possible by age, weight and genders to the subjects with renal impairment, Mean AUCo<sub>0</sub>—increased by
4%, 60%, and 115% in subjects with mild, moderate, and severe renal impairment, respectively,
compared to be alloy subjects. The entrinal elimination half-life increased by 18%, 41%, and 59% in
subjects with mild, moderate, and severe renal impairment, respectively, compared to be laid, 40% of the subjects. Hepatic Impairment

Memantine pharmacokinetics were evaluated following the administration of single oral doses of 20 mg

in 8 subjects with moderate bepatic impairment (Child-Pugh Class B, score 7-9) and 8 subjects who were age, gender-, and weight-matched to the bepatically-impaired subjects. There was no change in mensurine exposure (based on Cinax and AUC) in subjects with moderate bepatic impairment as compared with healthy subjects. However, terminal elimination half-life increased by about 16% in subjects with moderate hepatic impairment as compared with healthy subject as

# Drug-Drug Interactions

# Use with Cholinesterase Inhibitors

Coadministration of memartine with the AChE inhibitor done pezil did not affect the pharmacokinetics of either compound. Furthermore, memartine did not affect AChE inhibition by done pezil. In a 24-week controlled clinical study in patients with moderate to severe Alzheimer's disease, the adverse reaction profile observed with a combination of memartine immediate-release and done pezil was similar to that profile observed w of donepezil alone.

### Effect of Memantine on the Metabolism of Other Drugs

In vitro studies conducted with marker substrates of CYP450 enzymes (CYP1A2, -2A6, -2C9, -2D6, -2E5, -3A4) showed minimal inhibition of these enzymes by memartine. In addition, in vitro studies indicate that at concentrations exceeding those associated with efficacy, memarine does not induce the cytochrome P450 isozymes CYP1A2, -2C9, -2E1 and -3A445. No pharmacokinetic interactions with drugs metabolized by these enzymes are expected.

ungs inemotification by tiese exquites are textured to potential of memantine for interaction with warfarin and bupropion. Memantine did not affect the pharmacokinetics of the CVP2B6 substrate bupropion or its metabolite hydroxybupropion. Furthermore, memartine did not affect the pharmacokinetics or harmacodynamics of warfarin as assessed by the produrombin INR.

#### Effect of Other Druas on Memantine

Memantine is predominantly renally eliminated, and drugs that are substrates and/or inhibitors of the CYP450 system are not expected to alter the metabolism of memantine.

#### Drugs Eliminated via Renal Mechanisms

Drugs Eliminated via Renal Mechanisms

Because memuritie is eliminated in party bubular secretion, coadministration of drugs that use the same renal cationic system, including hydrochlororbinatide (HCTZ), triamterene (TA), metformin, cimetidine, ratificinie, quindine, and incoline, could potentially result in altered plasma levels of both agents. However, coadministration of memarine and HCT2/TA did not affect the bioavailability of either memarine or TA, and the bioavailability of HCTZ decreased by 20% in addition, coadministration of memarine with the antiprogregiveme drug Glucovance\* (g) buried and metformin hydrochloride) did memarine with the antiprogregiveme drug Glucovance\* (g) buried and metformin hydrochloride) did memarine with the antiprogregivement drugs glucovance of the pharmacodynamic interaction.

Most plant and the control of the pharmacodynamic interaction planting drugs and the pharmacodynamic interaction.

#### Drugs Highly Bound to Plasma Proteins

Because the plasma protein binding of memantine is low (45%), an interaction with drugs that are highly bound to plasma proteins, such as warfarin and digoxin, is unlikely.

#### 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

#### Carcinogenesis

There was no evidence of carcinogenicity in a 113-week or al study in mice at doses up to 40 mg/kg/day (7 times the maximum recommended human dosse [MRHD] on a mg/m² basis). There was also mo evidence of carcinogenicity in rato arolly dosed at up to 40 mg/kg/day for 71 weeks followed by 20 mg/kg/day (14 and 7 times the MRHD on a mg/m² basis, respectively) through 128 weeks. Mutagenesis

Memartine produced no evidence of genotoxic potential when evaluated in the in vitro S. sphimurium E. coli reverse mutation assay, an in vitro chromosomal aberration test in human lymphocytes, an in vivo cytogenetics assay for chromosome damage in rats, and the in vivo moste micronucleus assay. The results were equivocal in an in vitro gene mutation assay using Chinese hamster V79 cells.

### Impairment of Fertility

No impairment of fertility or reproductive performance was seen in rats administered up to 18 mg/kg/d9 (6 times the MRHD on a mg/m² basis) orally from 14 days prior to mating through gestation and lactation in females, or for 60 days prior to mating in males.

# 13.2 Animal Toxicology and/or Pharmacology

13.2 Animal Toxicology and/or Pharmacology
Memartine induced neuronal lesions (vacuolation and necrosis) in the multipolar and pyramidal cells in cortical layers III and IV of the posterior cirquitate and retrosplenial neocortices in rats, similar to those which are known to occur in roders administered other NMDA receptor anagonists. Lesions were seen after a single dose of memartine. In a study in which rats were given daily oral doses of memartine for 14 days, the mo-effect dose for reuronal necrosis was 4 dimes the maximum recommended human dose (MRHD of 28 mg/day) on a mg/m² basis.
In acute and repea-dose neurotoxicity studies in female rats, oral administration of memartine and donepezil in combination resulted in increased incidence, severity, and distribution of reurodegeneration compared with memartine alone. The mo-effect levels of the combination were associated with clinically relevant plasma memartine and donepezil exposures.

The relevance of these findings to humans is unknown.

# 14 CLINICAL STUDIES

The effectiveness of NAMENDA XR as a treatment for patients with moderate to severe Alzheimer's disease was based on the results of a double-blind, placebo-controlled trial.

#### 24-week Study of NAMENDA XR Capsules

24-week.Study of NAMKINDA XR Capsules

This was a randomized double-billed clinical investigation in outpatients with moderate to severe
Alzbeimer's disease (diagnosed by DSM-IV criteria and NINCDS-ADRDA criteria for AD with a Min
Menal State Examination (MMSE) score > 3 and 6 1 da Screening and Baseline receiving
a earylcholinesterase inhibitor (AChE) therapy at a stable dose for 3 months prior to screening. The
mean age of patients participating in this trial was 76.5 years with a range of 49-97 years.
Approximately 72% of patients were female and 34% were Caucasian.

The effectiveness of NAMENDA XR was evaluated in this study using the co-primary efficacy parameters of Severe Impairment Battery (SIB) and the Clinician's Interview-Based Impression of Change (CIBIC-Plus).

Charge (CIBIC-Plus). The ability of NAMENDA XR to improve cognitive performance was assessed with the Severe Impairment Battery (SiB), a multi-litem instrument that has been validated for the evaluation of cognitive function in patients with moderate to severe dementia. The SIB examines selected aspects of cognitive performance, including elements of attention, orientation, language, memory, visuospatial ability, construction, praxis, and social interaction. The SIB scoring range is from 0 to 100, with lower scores indicating greater cognitive impairment.

The ability of NAMENDA XR to produce an overall clinical effect was assessed using a Clinician's functioning greater opinive impairment.

The ability of NAMENDA XR to produce an overall clinical effect was assessed using a Clinician's flarerive Based impression of Change that required the use of caregiver information, the CIBIC-Plus. The CIBIC-Plus is not a single instrument and is not a standardized instrument like the ADCS-ADL or SIBIC-Plus is not a single instrument and surpaired a variety of CIBIC formas, each different in terms of depth and structure. As such, results from a CIBIC-Plus reflect clinical experience from the trial or trials in which it was used and cannot be compared directly with the results of CIBIC-Plus evaluations from other clinical trials. The CIBIC-Plus used in this trial was a structured instrument based on a comprehersive evaluation at baseline and susbequent time-points of four domains: general (overall clinical status), furniformal including activities of daily living), cognitive, and behavioral. It represents the assessment of a skilled clinical using validated scales based on hisher observation with the behavior of the palient over the interval rated. The CIBIC-Plus is scored as a seven point categorical rating, ranging from a score of 1, indicating "marked unoverseing." The CIBIC-Plus has not been systematically compared directly to assessments not using information from caregivers (CIBIC) or other global methods.

# Study Results

In this study, 677 patients were randomized to one of the following 2 treatments: NAMENDA XR 28 mg/day or placebo while still receiving an AChEI (either donepezil, galantamine, or rivastigmi

28 mg/day or placebo while still receiving an AChEI (either done)earl, galantamine, or rivasingmine). Effects on Severe Impairmer Battery (SB)

Figure 1 shows the time course for the change from baselline in SIB score for the too treatment groups completing the 24 weeks of the study. At 24 weeks of the reament, the most difference in the SIB Change scores for the NAMENDA XR 28 mg/AChEI-needed (combination therapy) patients compared to the patients on place bol/AChEI (monotherapy) was 26 units. Using an IACH analysis, NAMENDA XR 28 mg/AChEI renement was substitctedly significantly superior to placebol/AChEI.

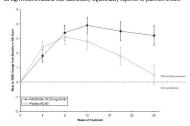


Figure 1: Time course of the change from baseline in SIB score for patients completing 24 weeks of treatment

Figure 2 shows the cumulative percentages of patients from each treatment group who had attained at least the measure of improvement in SIB scores shown on the X axis. The curves show that both patients assigned to NAMENDA XR 28 mg/AChE1 and paleod/AChE1 have a vide range of responses, but that the NAMENDA XR 28 mg/AChE1 group is more likely to show an improvement or a smaller decline.

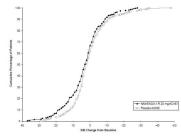


Figure 2: Cumulative percentage of patients completing 24 weeks of double-blind treatment with specified changes from baseline in SIB scores

Figure 3 shows the time course for the CIBIC-Plus score for patients in the two treatment groups completing the 24 weeks of the study. At 24 weeks of treatment, the mean difference in the CIBIC-Plus scores for the NAMENDA XR 28 mg/AChEI-read patients compared to the patients on placebot/AChEI was 0.3 units. Using an LOCF analysis, NAMENDA XR 28 mg/AChEI treatment was statistically significantly superior to placebot/AChEI.

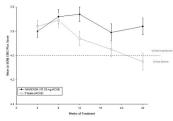


Figure 3: Time course of the CIBIC-Plus score for patients completing 24 weeks of treatment Figure 4 is a histogram of the percentage distribution of CIBIC-Plus scores attained by patients assigned to each of the treatment groups who completed 24 weeks of treatment.

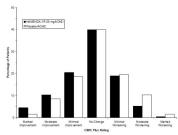


Figure 4: Distribution of CIBIC-Plus ratings at week 24

#### 16 HOW SUPPLIED/STORAGE AND HANDLING

7 mg Capsule

Yellow opaque capsule, with "FLI 7 mg" black imprint.

Bottle of 30: NDC# 0456-3407-33

Yellow cap and dark green opaque capsule with "FLI 14 mg" black imprint on the yellow cap.

Bottle of 30: NDC# 0456-3414-33 Bottle of 90: NDC# 0456-3414-90

2Ling Capaule.

White to off-white cap and dark green opaque capsule, with "FLI 21 mg" black imprint on the white to off-white and.

Bottle of 30: NDC# 0456-3421-33

28 mg Capsule

Dark green opaque capsule, with "FLI 28 mg" white imprint.

Bottle of 30: NDC# 0456-3428-33
Bottle of 90: NDC# 0456-3428-90
<u>Titration Pack</u> NDC# 0456-3400-29

Contains 28 capsules (7 x 7 mg, 7 x 14 mg, 7 x 21 mg, 7 x 28 mg)

Store NAMENDA XR at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

# 17 PATIENT COUNSELING INFORMATION

- Advise the patient to read the FDA-approved patient labeling (Patient Information).

  To assure safe and effective use of NAMENDA XR, the information and instructions provided in the patient information section should be discussed with patients and caregivers.

  Instruct patients and caregivers to take NAMENDA XR only once per day, as prescribed.

  Instruct patients and caregivers that NAMENDA XR capsules be swallowed whole. Alternatively, NAMENDA XR capsules my be opened and spirished on applesance and the entire contents should be consumed. The capsules should not be divided, chewed or crushed.

  Warm patients not to use any capsules of NAMENDA XR that are damaged or show signs of tamorine.
- waiti patients but to be any caponies of inviterable. An unit are training or on survey signs of if a patient riskes a single dose or (NAMENDA XR that patient should not double up on the next dose. The next dose should be taken as scheduled. If a patient fails to take NAMENDA XR for several days, doing should not be resumed without consulting that patient's healthcare professional.

  Advise patients and caregivers that NAMENDA XR may cause headache, diarrhea, and dizziness.

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Madison, NJ 07940

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Patented. See www.allergan.com/patents © 2019 Allergan. All rights reserved.

# NAMENDA XR® [Nuh-MEN-dah Eks-Are]

# (memantine hydrochloride) Extended-Release Capsules

Read this Patient Information that comes with NAMENDA  $XR^{in}$  before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

NAMENDA XR is a prescription medicine used for the treatment of moderate to severe dementia in people with Aizheimer's disease. NAMENDA XR belongs to a class of medicines called N-methyl-D-apparate (NMDA) inhibitors.

It is not known if NAMENDA XR is safe and effective inchildren.

# Who should not take NAMENDA XR?

Who should not take NAMENDA AR! you are allergic to memantine or any of the other ingredients in NAMENDA XR! you are allergic to memantine or any of the other ingredients in NAMENDA XR. See the end of this leaflet for a complete list of ingredients in NAMENDA XR. What should I tell my doctor before taking NAMENDA XR?\_

- Before you take NAMENDA XR, tell your doctor if you:

   have or have had seizures

   have or have had problems passing urine

- have or have had bladder or kidney problems

- have liver problems
  have any other medical conditions
  are pregnant or plan to become pregnant. It is not known if NAMENDA XR will harm your unborn
  baby.
- are breastfeeding or plan to breastfeed. It is not known if memantine passes into your breast milk.
   Talk to your doctor about the best way to feed your baby if you take NAMENDA XR.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Taking NAMENDA XR with certain other medicines may affect each other. Taking NAMENDA XR with other medicines can cause serious side effects.

Especially tell your doctor if you take:

• other NMDA antagonists such as amantadine, ketamine, and dextromethorphan

• medicines that make your urine alkaline such as carbonic arhydrase inhibitors and sodium bicarbonate

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

- new medicine.

  How should I take NAMENDA XR?

  Your doctor will tell you how much NAMENDA XR to take and when to take it.

  Your doctor may change your dose if needed.

  NAMENDA XR may be taken with food or without food.

  NAMENDA XR capsules may be opened and sprinded on applesance before swallowing, but the contents of the entire capsule should be taken and the dose should not be divided. Except when opened and sprinded on applesance, NAMENDA XR capsules must be swallowed whole and never crushed, divided or chewed.

  Do not use any capsules of NAMENDA XR that are damaged or show signs of tampering.

  If you are currently taking another formulation of menuntine, talk to your healthcare professional about how to switch to NAMENDAN XR.

- about how to switch to NAMENDA XR.

  If you forget to take one does of NAMENDA XR, do not double up on the next dose. You should take only the next dose as scheduled.

  If you have forgotien to take NAMENDA XR for several days, you should not take the next dose until you talk to your doctor.

  If you have for much NAMENDA XR, call your doctor or poison control center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

### What are the possible side effects of NAMENDA XR?

#### NAMENDA XR may cause side effects, including:

The most common side effects of NAMENDA XR include:

• headache
• diarrhea
• dizziness

These are not all the possible side effects of NAMENDA XR. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### How should I store NAMENDA XR?

Store NAMENDA XR at room temperatu

#### What are the ingredients in NAMENDA XR?

Active ingredient: memantine hydrochloride

Inactive ingredients: sugar spheres, polyvinylpyrrolidone, hypromellose, talc, polyethylene glycol, ethylcellulose, ammonium hydroxide, oleic acid, and medium chain triglycerides

### Keep NAMENDA XR and all medicines out of the reach of children

### General information about the safe and effective use of NAMENDA XR:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not take NAMENDA XR for a condition for which it was not prescribed. Do not give NAMENDA XR to other people, even if they have the same condition. It may harm them.

This Patient Information leaflet summarizes the most important information about NAMENDA XR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about NAMENDA XR that was written for healthcare professionals.

For more information about NAMENDA XR, go to www.namendaxr.com, or call Allergan at 1-800-678-1605

This Patient Information has been approved by the U.S. Food and Drug Administration.

Made in Ireland

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Revised: 11/2019

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# PRINCIPAL DISPLAY PANEL

NDC 0456-3407-33

30 capsules Rx only

Once-Daily Namenda XR® (memantine HCI) extended release capsules 7 mg



# PRINCIPAL DISPLAY PANEL

NDC 0456-3414-33 30 capsules Rx only

Once-Daily
Namenda XR®
(memantine HCI) extended release capsules
14 mg



# PRINCIPAL DISPLAY PANEL

NDC 0456-3414-90 90 capsules Rx only

Once-Daily
Namenda XR®
(memantine HCI) extended release capsules
14 mg



### PRINCIPAL DISPLAY PANEL

NDC 0456-3421-33 30 capsules Rx only

Once-Daily
Namenda XR®
(memantine HCI) extended release capsules
21 mg



#### PRINCIPAL DISPLAY PANEL

NDC 0456-3428-33 30 capsules Rx only

Once-Daily
Namenda XR®
(memantine HCI) extended release capsules
28 mg



### PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL
NDC 0456-3428-90
90 capsules
Rx only
Once-Daily
Namenda XR®
(memunine HCI) extended release capsules
28 mg



# PRINCIPAL DISPLAY PANEL

NDC 0456-3400-29 Titration Pack Once-Daily





| MEMANTINE HYDROCHLORIDE<br>UNIEW8 0 17 S J F 3 T)  | Ingredient Name E (UNII: JYOWD0 UA60) (memantine -   | Basis of Stre  | ngth Strength  |
|--|--|--|--|
|  |  | HYDROCHLORIDE  | ,  |
| Inactive Ingredients   | Ingredient Name  |  | Strength   |
| sucrose (UNII: C151H8M554)<br>povidone K30 (UNII: U725QWY32  | EX)  |  |  |
| hypromellose 2910 (15 MPA.S) (<br>talc (UNII: 7SEV7J4RIU)  | UNII: 36 SFW2JZ0W)   |  |  |
| polyethylene glycol 400 (UNII: B<br>POLYETHYLENE GLYCOL 800)   | 697894SGQ)   |  |  |
| ETHYLCELLULOSE (100 MPA.S  |  |  |  |
| AMMO NIA (UNII: 5138 Q 19 F1X)<br>O LEIC ACID (UNII: 2UMI9 U37CP)  |  |  |  |
| MEDIUM-CHAIN TRIGLYCERIDE<br>GELATIN (UNII: 2G86QN327L)  | ES (UNII: C9H2L21V7U)  |  |  |
|  |  |  |  |
| Product Characteristics Color YELLOW (   | rellow (opaque))   | Score  | no score   |
| Shape CAPSULE (  |  | Size   | 4mm<br>FLL7:mg   |
| Contains   |  | Imprint Code   | PLL(7)mg   |
|  |  |  |  |
| Packaging<br># Item Code   | Package Description  | Marketing Start Date M   | Marketing End Date   |
| 1 NDC:0456-3407-33 30 in 1 BO  | TTLE; Type 0: Not a Combination Product  | 10/31/2011   |  |
|  |  |  |  |
| Marketing Informatio   | ON<br>cation Number or Monograph Citation  | Marketing Start Date   | Marketine End Date   |
| NDA NDA022   |  | 10/31/2011   | ant acting Line Date   |
|  |  |  |  |
| NAMENDA XR<br>nemantine hydrochloride caps   | tule extended release  |  |  |
|  | sue, extended remase   |  |  |
| Product Information Product Type   | HUMAN PRESCRIPTION DRUG  | Item Code (Source)   | NDC:0456-3414  |
| Route of Administration  | ORAL ORAL  |  |  |
|  |  |  |  |
| Active Ingredient/Active !   |  | Basis of Stre  |  |
| MEMANTINE HYDROCHLORIDE<br>UNIEW8017SJF3T)   | Ingredient Name<br>E (UNII: JYOWD0 UA60) (memantine -  | MEMANTINE<br>HYDROCHLORIDE   | ngth Strength  |
| UNEWSO D'SJF31)  |  | HIDROCHLORDE   |  |
| Inactive Ingredients   |  |  |  |
| sucrose (UNII: C151H8M554)   | Ingredient Name  |  | Strength   |
| povidone K30 (UNII: U725QWY32  |  |  |  |
| hypromellose 2910 (15 MPA.S) (<br>talc (UNI: 7SEV7J4RIU)   |  |  |  |
| polyethylene glycol 400 (UNI: B<br>POLYETHYLENE GLYCOL 800   | 0 (UNII: Q662QK8M3B)   |  |  |
| ETHYLCELLULOSE (100 MPA.S<br>AMMONIA (UNII: 5138 Q 19 F1X)   | (UNII: 47MLB0F1MV)   |  |  |
| GELATIN (UNIE 2G86QN327L)<br>MEDIUM-CHAIN TRIGLYCERIDE   | PS (UNII) C9H2L2IV7ID  |  |  |
| O LEIC ACID (UNII: 2UMI9 U37CP)  |  |  |  |
|  |  |  |  |
| Product Characteristics Color YELLOW (yellow   | ) , GREEN (dark green (opaque))  | Score  | no score   |
| Shape CAPSULE (CAPS<br>Flavor  | ULE)   | Size<br>Imprint Code   | 4mm<br>FL1;14;mg   |
| Contains   |  |  |  |
| Packaging  |  |  |  |
| # Item Code  | Package Description  |  |  |
| 1 NDC:0456-3414-63 10 in 1 BOX<br>1 NDC:0456-3414-11 10 in 1 BLIS  | K, UNIT-DOSE<br>STER PACK; Type 0 : Not a Combination Proc   |  | 09/06/2016   |
| 2 NDC:0456-3414-33 30 in 1 BOT   | TTLE; Type 0: Not a Combination Product<br>TTLE; Type 0: Not a Combination Product   | 10/31/2011   |  |
|  |  | 10/31/2011   |  |
|  |  | 10/31/2011   |  |
| Marketing Informatio   | on   | 10/31/2011   |  |
| Marketing Category Appli   | cation Number or Monograph Citation  | Marketing Start Date 1   | Marketing End Date   |
| Marketing Category Appli   | cation Number or Monograph Citation  |  | Marketing End Date   |
| Marketing Category Appli NDA NDA022  NAMENDA XR  | cation Number or Monograph Citation<br>S2S   | Marketing Start Date 1   | Marketing End Date   |
| Marketing Category Appli NDA NDA022  NAMENDA XR  | cation Number or Monograph Citation<br>S2S   | Marketing Start Date 1   | Marketing End Date   |
| Marketing Category Appli NDA NDA0 22  NAMENDA XR memantine hydrochloride caps  Product Information   | cation Number or Monograph Citation<br>525<br>suk, extended release  | Marketing Start Date 1   |  |
| Marketing Category Appli NDA NDA022  NAMENDA XR memantine hydrochloride caps  Product Information  Product Type  | cation Number or Monograph Citation 525 sule, extended release HRIMAN PRESCRIPTION DRUG  | Marketing Start Date 1   |  |
| Marketing Category Appli NDA NDA022  NAMENDA XR memantine hydrochloride caps  Product Information  Product Type  | cation Number or Monograph Citation<br>525<br>suk, extended release  | Marketing Start Date 1   |  |
| Marketing Category Appli NDA 2  NAMENDA XR  NAMENDA XR  memantine hydrochloride caps  Product Information  Product Type  Route of Administration   | cation Number or Monograph Citation 222  Suile, extended release  MEMAN PRESCRIPTION DRUG  ORAL  | Marketing Start Date 1   |  |
| Marketing Category Appll NDA   | cation Number or Monograph Citation 232  sule, extended release  HEMAN PRESCRIPTION DRUG  ORAL  Molety  Ingredient Name  | Marketing Start Date 1 10/1/2011  Item Code (Source)  Basis of Stre  | NDC:9456-3421  |
| Marketing Category Appli NDA  NDA  NDA  NDA  NDA  NDA  NDA  NDA  | cation Number or Monograph Citation 335  Mule, extended release  MEMAN PRESCRIPTION DRUG  ORAL  Molety   | Marketing Start Date 3 100/31/2011   | NDC:0456-3421  |
| Marketing Category Appli NOA022  NAMENDA XR  Remaintine hydrochloride caps  Product Information  Product Type Route of Administration  Active Ingredient/Active 1  MEMARKETER ROUTE (FORDS)  | cation Number or Monograph Citation 232  sule, extended release  HEMAN PRESCRIPTION DRUG  ORAL  Molety  Ingredient Name  | Marketing Start Date 3 | NDC:9456-3421  |
| Marketing Category Appli NOA022  NAMENDA XR  Remaintine hydrochloride caps  Product Information  Product Type Route of Administration  Active Ingredient/Active 1  MEMARKETER ROUTE (FORDS)  | cation Number or Monograph Citation 335  iule, extended release  HUMAN PRESCRIPTION DRUG  ORAL  Molety Ingredient Name  (UNIL IVWWDD UM60) (memanine -   | Marketing Start Date 3 | NDC:0456-3421  ngth Strengtl 21 mg   |
| MARKETING CATEGORY NDA NAMENDA XR nemantine bydrochloride cape Product Information Product Information Active Ingredient/Active 1 MIMANTINI HYDROCHLORIDE UNDRWGOLFSJETI Inactive Ingredients NECONIC CESTERNESS 6   | cation Number or Monograph Citation 335  sule, extended release  HUMAN PRESCRIPTION DRUG  ORAL  Molety  Ingredient Name  Ingredient Name   | Marketing Start Date 3 | NDC:9456-3421  |
| Marketing Category Appli NDA 921 NDA 922 NDA 9 | cation Number or Monograph Citation 232 332 342 342 343 344 345 345 345 345 345 345 345 345  | Marketing Start Date 3 | NDC:0456-3421  ngth Strengtl 21 mg   |
| Marketing Category Appli NDA   | cation Number or Monograph Citation 535  inle, extended release  HUMAN PRESCRIPTION DRUG  ORAL  Molety Ingredient Name (UNIL 1999/190 UMO) (memanine -  Ingredient Name  EX)  UNIL SISPACIZION) 607294845(2)   | Marketing Start Date 3 | NDC:0456-3421  ngth Strengtl 21 mg   |
| Marketing Category Appl NDA NDA022 NAMENDA XR memantine hydrochloride Capa Product Information Product Type Route of Administration Active Ingredient/Active I MEMANTINE HYDROCHLORIDE UNREWSO DESIFEST) Inactive Ingredients success (URIN CESSIBMS55) hyperadition 2018 (IS MPAS) hypera | Cation Number or Monograph Citation 2323  IRAMAN PRESCRIPTION DRUG ORAL  Molety Ingredient Name (UNIL 170WID ULGO) (memanine -  UNIL SESPEZIZOW) 08789852(2) (UNIL 9628/SMMS)  | Marketing Start Date 3 | NDC:0456-3421  ngth Strengtl 21 mg   |
| Marketing Category Appl NDA  NDA  NDA  NDA  NDA  NDA  NDA  NDA   | Cation Number or Monograph Citation 232  Mule, extended release  MIMAN PRESCRIPTION DRUG ORAL  Molety Ingredient Name (UNIL // YOWN DO UA60) (memanine -  Ingredient Name (UNIL // YOWN DO UA60) (memanine -  233) UNIL 865FW21ZOV) (UNIL 870E.BOPTIMY)  | Marketing Start Date 3 | NDC:0456-3421  ngth Strengtl 21 mg   |
| NAMENDA XR memantine hydrochlorate caps Product Information Product Type Boate of Administration Boate of Administration Boate of Administration  Active Ingredient/Active !  MEMANTINE RIPBOCHLORINE LUNBWIGGENERAL LUNBWIGGENERAL Superside (UNIL CISSIBMOS) pavidance K10 (UNIL U725(WYL) LUNBWIGGENERAL Superside (UNIL U725(WYL) LUNBWIGGENERAL Superside (UNIL U725(WYL) LUNGWIGGENERAL Superside (UNIL U725(WYL) LUNGWIGGENERAL Superside (UNIL U725(WYL) LUNGWIGGENERAL Superside (UNIL UTS) LUNGWIGGENERA | CAMEN Number or Monograph Citation 2525  MILMAN PRESCRIPTION DRUG ORAL  Molety  Molety  Ingredient Name (ONEL POWNED UM60) (memanine - UNEL SIGNED STREET, COMEN C | Marketing Start Date 3 | NDC:0456-3421  ngth Strengtl 21 mg   |
| Marketing Gategory Appl NDA  NDA  NDA  NDA  NDA  NDA  NDA  NDA   | CAMEN Number or Monograph Citation 2525  MILMAN PRESCRIPTION DRUG ORAL  Molety  Molety  Ingredient Name (ONEL POWNED UM60) (memanine - UNEL SIGNED STREET, COMEN C | Marketing Start Date 3 | NDC:0456-3421  ngth Strengtl 21 mg   |
| Marketing Gategory Appl NDA  NAMENDA XR memantine hydrochloride capa  Product Information  Product Type Route of Administration  Active Ingredient/Active I  MEMANYTNE HYDROCHLORIDE  UNREWOOTS-JEFT)  Inactive Ingredients  successe (UNR CESHRMES-9)  particular Staff (UNR UTZS)(WYZL)  Supermediase 218 (UNR UTZS)(WYZL)  Supermediase 218 (UNR UTZS)(WYZL)  Product Character (UNR UTZS) (WYZL)  DIEC ACID (UNR UTZS) (18 MRAS) (UNIVERSITY (UNIV | Cation Number or Monograph Citation 232  BILLIAN PRESCRIPTION DRUG ORAL  Molety Ingredient Name (UNIL 170WIDD UA60) (menunina -  Ingredient Name (UNIL 2000) (UNIL | Marketing Start Date   10/21/2011   10/21/20 | NDC-0456-3421 ingth Strength 21 mg   |
| MARKETING CARE ON A PAPE NO A PARE N | CAMEN Number or Monograph Citation 2525  MEMAN PRESCRIPTION DRUG ORAL  Meiery Ingredient Name (CNRL PYMWOULMO) (memanina -  LING SCRIPTION) (UNRL SCRIPTION)   | Marketing Start Date   3<br> 30:30011  | NDC:0456-3421  ngth Strength 21 mg   |
| MARKETING CARE ON A PAPER OF THE CALL OF T | CAMEN Number or Monograph Citation 2525  MEMAN PRESCRIPTION DRUG ORAL  Meiery Ingredient Name (CNRL PYMWOULMO) (memanina -  LING SCRIPTION) (UNRL SCRIPTION)   | Markeding Start Daire   1<br>  10/12/011   | NDC-9-456-3-421  mgth Strength  21 mg  |
| MARKETING CARE ON A PAPER OF THE CALL OF T | CAMEN Number or Monograph Citation 2525  MEMAN PRESCRIPTION DRUG ORAL  Meiery Ingredient Name (CNRL PYMWOULMO) (memanina -  LING SCRIPTION) (UNRL SCRIPTION)   | Markeding Start Daire   1<br>  10/12/011   | NDC:0456-3421  Ingth Strength  21 mg  Strength  an score an accore                                 |
| MARKETING CARE CAPE OF THE CAP | CAMEN Number or Monograph Citation 2525  MEMAN PRESCRIPTION DRUG ORAL  Meiery Ingredient Name (CNRL PYMWOULMO) (memanina -  LING SCRIPTION) (UNRL SCRIPTION)   | Markeding Start Daire   1<br>  10/12/011   | NDC:0456-3421  Ingth Strength  21 mg  Strength  an score an accore                                 |
| Marketing Category Appl NAMENDA XR  NAMENDA XR  Product Indromation  Product Type Route of Administration  Product Ingredient/Active 1  MEMANTEN INDROCEL ORDIN  MEMANTEN INDROCEL  MEMANTEN  MEMANTEN | Cation Number or Monograph Citation 2525  ILLIMAN PRESCREPTION DRUG ORAL  Molety  Molety  Ingredient Name (USB. MANYPESCREPTION DRUG ORAL  Ingredient Name (USB. MANYPESCREPTION DRUG ORAL MOVED UMO) (mensorine -  Ingredient Name (USB. MANYPEZZON)  ORAL MANYPEZZON  (USB. GESZORAMI) (USB. GESZORAM | Marketing Start Date   1   | NDC-0406-3421  ngth Strength  Strength  in 65097  an FA221mg                                       |
| Marketing Category Appl NAMENDA XR  NAMENDA XR  Product Indromation  Product Type Route of Administration  Product Ingredient/Active 1  MEMANTEN INDROCEL ORDIN  MEMANTEN INDROCEL  MEMANTEN  MEMANTEN | Academ Number or Monograph Citation 2525  MEMAN PRESCRIPTION DRUG ORAL  Molety Ingredient Name (UNB. 1988-022094)  LING SERVIZION)  (UNB. 2588-022094)  (UNB. 2588-022 | Marketing Start Date   1   | NDC-0406-3421  ngth Strength  Strength  in 65097  an FA221mg                                       |
| Marketing Gategory Appl NDA022  NAMENDA XR memantine hydrochloride caps Product Information Product Tofromation Product Gategory MEMANATION PRODUCTION PRODUCTION OF TOTROCOMMENT P | Action Number or Monograph Citation 2525  MEMAN PRESCRIPTION DRUG ORAL  Molecy Ingredient Name (UNB. 1987042709)  LING 2687043709  (UNB. 2687042709)  (UNB. 2687043709)  (UNB. 268704709)  (UNB. 268704709)  (UNB. 268704709)  (UNB. 268704709)  (UNB. 268704709)  ( | Marketing Start Date   1   | NDC:0406-3421  ngth Strength  Strength  in 66007  dam  fil.221mg                                   |
| MARKETING CAREGOV APPLICATION OF THE CAREGORY APPLICATION  | Action Number or Monograph Citation 2525  MEMAN PRESCRIPTION DRUG ORAL  Molecy Ingredient Name (CORL POWNOULAGO) (memanina - LIngredient Name (CORL POWNOULAGO) (memanina - (CORL POWNOULAGO) (memanina - LING SCRIPTION DRUG ) (LORG SCRIPTION DRUG ) (CORL POWNOULAGO) (memanina - LORG SCRIPTION DRUG ) (CORL POWNOULAGO) ( | Marketing Start Date   3   10:01/2011  | NDC.0466-3421  Ingth Strength  21 mg  Strength  In according to darketing End Date.                |
| MARKETING CAREGOV APPLICATION OF THE CAREGORY APPLICATION  | Action Number or Monograph Citation 2525  MEMAN PRESCRIPTION DRUG ORAL  Molecy Ingredient Name (CORL POWNOULAGO) (memanina - LIngredient Name (CORL POWNOULAGO) (memanina - (CORL POWNOULAGO) (memanina - LING SCRIPTION DRUG ) (LORG SCRIPTION DRUG ) (CORL POWNOULAGO) (memanina - LORG SCRIPTION DRUG ) (CORL POWNOULAGO) ( | Marketing Start Date   10/12/011    Brain Cade (Source)  Basis of Street   10/12/011    Basis of Street   10/12/011    Basis of Street   10/12/011    Score   10/12/011    Marketing Start Date   3/12/011    Marketing Start Date | NDC.0466-3421  Ingth Strength  21 mg  Strength  In according to darketing End Date.                |
| MARKETING CATE GOVERNOR  NAMENDA XR  Product Information  Product Type  Route of Administration  Product Type  Route of Administration  Active Ingredient/Active 1  MIMANTEN INDROCH GRID  URBWOOTS-INGRED  INGRED  IN | Action Number or Monograph Citation 2525  MEMAN PRESCRIPTION DRUG ORAL  Molecy Ingredient Name (CORL POWNOULAGO) (memanina - LIngredient Name (CORL POWNOULAGO) (memanina - (CORL POWNOULAGO) (memanina - LING SCRIPTION DRUG ) (LORG SCRIPTION DRUG ) (CORL POWNOULAGO) (memanina - LORG SCRIPTION DRUG ) (CORL POWNOULAGO) ( | Marketing Start Date   3   10:01/2011  | NDC.0466-3421  Ingth Strength  21 mg  Strength  In according to darketing End Date.                |
| MARKETING CATEGORY  ANAMENDA XR  memantine hydrochloride caps  Product Information  Product Tofromation  Inactive Ingredient/Active !  MINIMATERIAL (INGREDIENT STATEMENT STATE | Action Number or Monograph Citation 2525  MEMAN PRESCRIPTION DRUG ORAL  Moiety Ingredient Name (CORL / YOWN ULMO) (memanine - LING SESPREJIZON) (UND SESPREJIZON) (UND GESPREJIZON) (UND GESPREJ | Marketing Start Date   3   10:01/2011  | NDC.0466-3421  Ingth Strength  21 mg  Strength  In according to darketing End Date.                |
| MARKETING CAREGOV APPLICATION OF THE CAREGORY APPLICATION  | Action Number or Monograph Citation 2325  BIEMAIN PRESCRIPTION DRUG ORAL  Molety Ingredient Name (UNE 197047000 (Internation -  UNE 287047000) (UNE 2870470000) (UNE 2870470000000000000000000000000000000000  | Marketing Start Date   10-01/2011  Bran Cede (Source)  Basis of Stre   MARANTINE   10-01/2011  Score   Size   Imprint Cede   I | NDC.0458-3421  ngth Strength  21 ng  Strength  no score  den R.1J7mg  Fr.1J7mg  Marketing End Date |
| MARKETING CATE GOVERNORM  NOAMENDA XR memantine hydrochloride caps  Product Information  Praduct Type Route of Administration  Active Ingredient/Active !  MINIMATERIA (Type Route of Administration  Active Ingredient/Active !  MINIMATERIA (Type Route of Administration  Active Ingredient/Active !  MINIMATERIA (Type Route of Administration  LINGWOODS/FIT)  Inactive Ingredients  uncrease (UNIN U7250/WV22  MINIMATERIA (UNIN U7250/WV22  MARKET (UNI | action Number or Monograph Citation 2525  MUMAN PRESCRETTON DRUG ORAL  Molety Ingredient Name (ONE. YOPEN DRUG) (ONE. SAME OF THE ORAL OF  | Marketing Start Date   3   10:01/2011  | NDC.0458-3421  ngth Strength  21 ng  Strength  no score  den R.1J7mg  Fr.1J7mg  Marketing End Date |
| Marketing Gasegory Appl NDA  NDA  NDA  NDA  NDA  NDA  NDA  NDA   | Action Number or Monograph Citation 2325  BIEMAIN PRESCRIPTION DRUG ORAL  Molety Ingredient Name (UNE 197047000 (Internation -  UNE 287047000) (UNE 2870470000) (UNE 2870470000000000000000000000000000000000  | Marketing Start Date   10-01/2011  Bran Cede (Source)  Basis of Stre   MARANTINE   10-01/2011  Score   Size   Imprint Cede   I | ngth Strengt 21 mg Strength  Strength  so score 4 mm Fix22 mg  Marketing End Date                  |

Active Ingredient/Active Moiety
Ingredient Name
Basis of Strength
MEMANTER HYDROCHLORIDE (UNIL )YOWDOUA60) (memantine UNILWO O'ESFET)
HYDROCHLORIDE
22 mg

Inactive Ingredients

|  | 31H8M554)<br>NII: U725QWY32X)  |  |  |
|--|--|--|--|
|  | 10 (15 MPA.S) (UNII: 36 SFW2JZ0W)  |  |  |
| polyethylene glyc  | col 400 (UNII: B697894SGQ)  GLYCOL 8000 (UNII: Q662QK8M3B)   |  |  |
| ETHYLCELLULO   | SE (100 MPA.S) (UNII: 47MLB0F1MV)  |  |  |
| AMMONIA (UNII:<br>O LEIC ACID (UNI   |  |  |  |
|  | FRIGLYCERIDES (UNII: C9H2L21V7U)   |  |  |
| Dundant Ct   | actaulatics  |  |  |
| Product Char<br>Color<br>Shape   | GREEN (dark green (opaque))  CAPSULE (CAPSULE)   | Score<br>Size  | no score<br>3mm  |
| Snape<br>Flavor<br>Contains  |  | Imprint Code   |  |
| Contains   |  |  |  |
| Packaging<br># Item Code   | Package Description  | Marketing Start Date   | Marketing End Date   |
| NDC:0456-3428  | -63 10 in 1 BOX, UNIT-DOSE<br>-11 10 in 1 BLISTER PACK; Type 0: Not a Combination Proc   | 10/31/2011   | 09/06/2016   |
| NDC:0456-3428  | -33 30 in 1 BOTTLE; Type 0: Not a Combination Product  | 10/31/2011   |  |
| NDC:0456-3428<br>90  | 90 in 1 BOTTLE; Type 0: Not a Combination Product  | 10/31/2011   |  |
|  | Information gory Application Number or Monograph Citation NDA022525  | Marketing Start Date   | Marketing End Date   |
| NDA  | NUA022525  | 10/31/2011   |  |
| NAMENDA<br>nemantine hydro   |  |  |  |
| Product Infor  | mation   |  |  |
| Product Type   | HUMAN PRESCRIPTION DRUG Item   | Code (Source)  | NDC:0456-3400  |
| Packaging    Item Code   NDC:0456-3400   | Package Description 1-29 1 in 1 BLISTER PACK; Type 0: Not a Combination Produ  | Marketing Start Date   | Marketing End Date   |
| Quantity of Pa   | sate   |  |  |
|  | Package Quantity 7   | Total Product Quar   | itity  |
| Part 2<br>Part 3   | 7 7  |  |  |
| Part 3<br>Part 4   | 7  |  |  |
|  |  |  |  |
| Part 1 of 4  |  |  |  |
| NAMENDA  | XR ochloride capsule, extended release   |  |  |
| manuse nydi  |  |  |  |
| Product Infor  | mation   |  |  |
|  | stration ORAL  |  |  |
| A salous You would   | lond/Anthon Malano   |  |  |
|  | ient/Active Moiety<br>Ingredient Name  | Basis of S   | trength Strength   |
| memantine hydro  | chloride (UNII: JYO WDO UA60) (memantine - UNII:W8 O 17S.  | (F3T) memantine hydr   | rochloride 7 mg  |
| Inactive Ingre   | dients   |  |  |
|  |  |  |  |
| sucrose (UNII: C15   | Ingredient Name  |  | Strength   |
| povidone K30 (U  | 1H8M554)<br>NII: U725QWY32X)   |  | Strength   |
| povidone K30 (U<br>hypromellose 29:<br>talc (UNII: 7SEV7)  | IHBM554)<br>NIE U725QWY32X)<br><b>10 (15 MPA.S)</b> (UNIE 36SFW2JZ0W)  |  | Strength   |
| povidone K30 (U<br>hypromellose 29:<br>talc (UNI: 7SEV7)<br>polyethylene glyc<br>polyethylene glyc<br>polyethylene glyc  | IHBMS54 (WY32X) INE U725QWY32X) IO (15 MPA-S) (UNR: 36SFW2JZOW) 4RIU) ol 406 (UNR: 8697894SGQ) ol 406 (UNR: 8697894SGQ)  |  | Strength   |
| povidone K30 (U<br>hypromellose 29:<br>talc (UNII: 7SEV7)<br>polyethylene glyc<br>polyethylene glyc<br>ethylcellulose (10  | IHEMASS4) NO (15 MPR-AS) (UNIR 36 SFW21Z8W) 10 (15 MPR-AS) (UNIR 36 SFW21Z8W) 4RUJ 14RUJ 14RUJ 14B0 (UNIR 1869 789 48CQ) 14B0 (UNIR 1662 QKBMB) 10 MPR-AS) (UNIR 47 MERBEFINN)   |  | Strength   |
| ovidone K30 (U. sypromellose 29: alc (UNII: 7SEV7.) solyethylene glycolyethylene glycolyethylene glycolyethylene (10 smmonia (UNII: 5 DLEIC ACID (UNI  | NIBMEST(4)  NR UTZSGWYCZE)  18 (15 MPA-S) (UNR 36 SFW2JZZW)  4 REC   14 SE (UNR 16 SFW2JZZW)  4 18 SE (UNR 16 SFZW3JZZW)  4 18 SE (UNR 16 SFZW3JZZW)  5 SE (UNR 16 SFZW3JZW)  5 SE (UNR 16 SFZW3JZW)  18 UNR 16 UNR 16 SFZW3JZW)  18 UNR 17 UNR  |  | Strength   |
| povidone K30 (U<br>hypromellose 29:<br>ialc (UNI: 7SEV7.)<br>polyethylene glyc<br>polyethylene glyc<br>ethylcellulose (10<br>ammonia (UNI: 5<br>D LEIC ACID (UNI<br>MEDIUM-CHAIN 1   | INBENDES    WE UT-ZSSMYZZZNY  18 (15 SAPA-SE (UNIE RAS FRYZZZNY)  448U)  14 480 (UNIE RAS FRYZZZNY)  14 480 (UNIE RAS FRYZZZNY)  19 SAPA-SE (UNIE CENEROPINA)  19 SAPA-SE (UNIE CENEROPINA)  18 SAPA-SE (UNIE CENEROPINA)  18 ZUMBUJECTO;  18 ZUMBUJECTO;  |  | Strength   |
| povidene K30 (U<br>hypromellose 29:<br>late (UNE: 'SEV71<br>polyethylene glyc<br>polyethylene glyc<br>polyethylene glyc<br>sthylcellulose (16<br>ammonia (UNE: 5<br>DLEIC ACID (UNI<br>MEDIUM-CHAIN 1<br>GELATIN (UNI: 2   | INBERGES    NE U7250YVZZX)  NE U7250YVZZX  16 U53 MPAS, (UNB. 368FW21ZZW)  41810;  14 1880 (UNB. 19678545CQ)  14 1880 (UNB. 19678545CQ)  14 1880 (UNB. 19678645CQ)  15 1880 (UNB. 19678667EW)  15 1880 (UNB. 19678667EW)  16 1880 (UNB. 1967867EW)  17 1880 (UNB. 1967867EW)  17 1880 (UNB. 1967867EW)   |  | Strength   |
| povidone K30 (U<br>hypromellose 29:<br>tale (UNIE 7SEV2)<br>tale (UNIE 7SEV2)<br>polyethylene glyc<br>polyethylene glyc<br>polyethylene glyc<br>thylcellulose (16:<br>ammonia (UNIE 5:<br>ammonia (UNIE 2:<br>DLEIC ACID (UNI<br>MEDIUM-CHAIN 1<br>GELATIN (UNIE 2:  | INBENDS    NEUTZSGWYYZZN    NEUTZSGWYYZZN    NEUTZSGWYZZN    NEUTZSGWYZN    NEUTZSGWY | Score  |  |
| povidone K30 (U<br>hypromellose 29:<br>Late (UNIE: 752)<br>polyethylene glyc<br>polyethylene glyc<br>thylcellulose (IC<br>ammonia (UNIE: 5<br>DLEIC ACID (UNI<br>MEDIUM-CHAIN: 3<br>GELATIN (UNIE: 2<br>Product Char-<br>Color<br>Shape  | INBERGES    NE U7250YVZZX)  NE U7250YVZZX  16 U53 MPAS, (UNB. 368FW21ZZW)  41810;  14 1880 (UNB. 19678545CQ)  14 1880 (UNB. 19678545CQ)  14 1880 (UNB. 19678645CQ)  15 1880 (UNB. 19678667EW)  15 1880 (UNB. 19678667EW)  16 1880 (UNB. 1967867EW)  17 1880 (UNB. 1967867EW)  17 1880 (UNB. 1967867EW)   | Size   | 50 SCORE<br>14mm   |
| povidone K30 (U<br>hypromellose 29:<br>tale (UNIE: 7SEV7)<br>polyethylene glyc<br>polyethylene glyc<br>thylcellulose (If<br>ammonia (UNIE: 5)<br>D.LEIC ACID (UNI<br>MEDIUM-CHAIN: 1<br>GELATIN (UNIE: 2<br>Product Char-<br>Color<br>Shape  | NEMESCÉS DE L'ESTRUZZONO  10 (13 MANSA (UNE SESTRUZZONO)  10 (13 MANSA (UNE SESTRUZZONO)  11 488 (UNE BESTRUZZONO)  11 488 (UNE BESTRUZZONO)  11 488 (UNE BESTRUZZONO)  11 MANSA (UNE BESTRUZZONO)  12 MANSA (UNE BESTRUZZONO)  12 MANSA (UNE CONFELLIVITU)  CERCONOZZONO  CERCONOZZONO  WILLOW (UPELLOW (UPAQUEE)   |  | Do score   |
| povidone K30 (U ypromelios 23) on<br>Vypromelios 23) on<br>povidone K30 (URL 782V) polytyhylene glycolythylene glyc | INBEMS_16  RE UTZ-50/WYZEX )  RE UTZ-50/WYZEX )  RE UTZ-50/WYZEX  RE UTZ-50/WYZEX  RE UTZ-50/WYZEX  RE UTZ-50/WYZEX  RE UTZ-50/WZEX  RE UTZ-50 | Size   | 50 SCORE<br>14mm   |
| povidene K39 (U. Nypromellos 29:  Late (UNR 758V) polyenhytene gly- polyenhytene gly- polyenhytene gly- polyenhytene gly- thytecellasse (H.  memoria (UNI: 8-  DLEIC ACID (UNI: 8-  DLEIC ACID (UNI: 9-  DLEIC ACID (UNI: 9     | INBOGS JO  RE UZSGWYZZN  RE UZSGWYZZN  RE US SAWAS (UNB SASTWZZZWW)  48100  18 08 CHAS (UNB ESTWZZZWW)  18 18 08 CHAS (UNB ESTWZZZWW)  18 08 CHAS (UNB ESTWZZZWW)  18 08 CHAS (UNB ESTWZZZWARIE)  18 08 CHAS (UNB ESTWZZWARIE)  18 08 CHAS (UNB ESTWZZWARIE | Size Imprint Code  Marketing Start Date  | 80 SCOTE<br>Hamm<br>FLE7;mg  |
| povidene K39 (U. Nypromellos 29:  Late (UNR 758V) polyenhytene gly- polyenhytene gly- polyenhytene gly- polyenhytene gly- thytecellasse (H.  memoria (UNI: 8-  DLEIC ACID (UNI: 8-  DLEIC ACID (UNI: 9-  DLEIC ACID (UNI: 9     | NEMESCH SE STRUCTURE SERVICE S | Size<br>Imprint Code   | 80 SCOTE<br>Hamm<br>FLE7;mg  |
| povidane K19 (U. Whypmenline S)  take (UNE 75EV7)  polyshytem glycolythirm glycolyt     | INBOGS JO  RE UZSGWYZZN  RE UZSGWYZZN  RE US SAWAS (UNB SASTWZZZWW)  48100  18 08 CHAS (UNB ESTWZZZWW)  18 18 08 CHAS (UNB ESTWZZZWW)  18 08 CHAS (UNB ESTWZZZWW)  18 08 CHAS (UNB ESTWZZZWARIE)  18 08 CHAS (UNB ESTWZZWARIE)  18 08 CHAS (UNB ESTWZZWARIE | Size Imprint Code  Marketing Start Date  | 80 SCOTE<br>Hamm<br>FLE7;mg  |
| pavidane K19 (U. Mygraellae V.     | INBENDES    RE UTZSOPYYEXN  RE UTZSOPYYEXN  RE UTS SERVEZZOW)  41 618 FURS BESTREZZOW)  41 618 FURS BESTREZZOW)  41 618 FURS BESTREZZOW  15 180 FURS BESTREZZOW  15 180 FURS BESTREZZOW  18 180 FURS BESTREZZOW  18 180 FURS BESTREZZOW  18 180 FURS BESTREZZOW  18 180 FURS FURS CONTROLLED  18 18 FURS FURS CONTROLLED  18 18 FURS FURS FURS CONTROLLED  18 FURS FURS FURS FURS FURS FURS FURS FURS  | Size Imprint Code  Marketing Start Date  | 80 SCOTE<br>Hamm<br>FLE7;mg  |
| yavidana K19 (U. Myyamida K19 (U. Myyami     | INBECTS OF THE STATE OF THE STA | Size Imprint Code  Marketing Start Date  | 80 SCOTE<br>Hamm<br>FLE7;mg  |
| posidose X19 (U. Myspenellos 22 palate (UNIA 75EV/Japanellos 2     | INBECTS OF THE STATE OF THE STA | Size Imprint Code  Marketing Start Date  | 80 SCOTE<br>Hamm<br>FLE7;mg  |
| povidane K10 (U. Nypromiller 2)  Lake (U.NE. 75K-71)  Lake (U.NE. 75K-71     | INBECTION OF THE ACT O | Size Imprint Code  Marketing Start Date  | 80 SCOTE<br>Hamm<br>FLE7;mg  |
| povidence K10 (U. Nypromition 2) and the Control of     | INBESTED  RE UTZSGYVYZXN  RE UTZSGYVYZXN  RE UTZSGYVYZXN  RE UT US STANDA (UNE SASTWZZZOW)  AL US US UNE BASTWZZZOW)  AL US US UNE BASTWZZZOW  AL US   | Size Imprint Code Imprint Code  Marketing Start Date 09/15/2011  Basis of S                                      | no score   |
| povidence K10 (U. Nypromition 2) and the Control of     | INBOCAS OF THE PROPERTY OF THE | Size Imprint Code Imprint Code  Marketing Start Date 09/15/2011  Basis of S                                      | 80 score  14mm  FLA7mg  Marketing End Date   |
| pavidane K19 (U. Nyprometica 2) at a (U. Nat. 2) at a (U.     | INBECTION OF THE CAPACITY OF T | Size Imprint Code Imprint Code  Marketing Start Date 09/15/2011  Basis of S                                      | no score  Jamm Fl.k7:mg  Marketing End Date  Marketing End Date  Strength  Strength  Jama  Jama  Jama  Jama  Jama  |
| povidence X19 (U. Nyspermellor 29 Jacks (U.NR 25X-V).  Jacks (U.NR 25X-V     | INBENESS    NEW U7250YYUZN)  10 (13 SWAS (UNB 36SFW21Z0W)  4810    11 610 SWAS (UNB 36SFW21Z0W)  4810    11 610 SWAS (UNB 36SFW21Z0W)  11 610 SWAS (UNB 867FW25CQ)  11 610 SWAS (UNB 867FW25CQ)  11 610 SWAS (UNB 867FW7)  12 610 SWAS (UNB 867FW7)  13 610 SWAS (UNB 867FW7)  14 610 SWAS (UNB 867FW7)  15 610 SWAS (UNB 867FW7)  16 610 SWAS (UNB 867FW7)  16 610 SWAS (UNB 867FW7)  17 610 SWAS (UNB 867FW7)  18 610  | Size Imprint Code Imprint Code  Marketing Start Date 09/15/2011  Basis of S                                      | no score   |
| povidence X19 (U. Nyspermellors 2)  Jack (UNIS 2)  Product Charcole  Jack (UNIS 2)  Product Charcole  Jack (UNIS 2)  Jack (UNI     | INDEXESSA (UNIL SASTIVAZZON)  18 (18 SEMANS, (UNIL SASTIVAZZON)  18 (18 SEMANS, (UNIL SASTIVAZZON)  18 (18 SEMANS, (UNIL SASTIVAZZON)  18 SERVER (UNIL SASTIVAZZON)  18 (18 SEMANS, (UNIL SASTIVAZZON))  | Size Imprint Code Imprint Code  Marketing Start Date 09/15/2011  Basis of S                                      | no score  Jamm Fl.k7:mg  Marketing End Date  Marketing End Date  Strength  Strength  Jama  Jama  Jama  Jama  Jama  |
| pavidane K19 (U. Nypremeller 2) yalake (UNR 75EV). Jalake (UNR 75EV).      | INDERESSION  REUTZIONYUZN  REU | Size Imprint Code Imprint Code  Marketing Start Date 09/15/2011  Basis of S                                      | no score  Jamm Fl.k7:mg  Marketing End Date  Marketing End Date  Strength  Strength  Jama  Jama  Jama  Jama  Jama  |
| pavidane K19 (U. Mypremellers 2) attack (U.M. 75EV.) attack (U.M.      | INDERESSION  REUTZSOPYTENN  REUTZSOP | Size Imprint Code Imprint Code  Marketing Start Date 09/15/2011  Basis of S                                      | no score  Jamm Fl.k7:mg  Marketing End Date  Marketing End Date  Strength  Strength  Jama  Jama  Jama  Jama  Jama  |
| pavidane K19 (U. Nypromeline 2) atala (UNIX 2) atal     | INDIVIDUAL OF THE PROPERTY OF  | Size Imprint Code Imprint Code  Marketing Start Date 09/15/2011  Basis of S                                      | no score  Jamm Fl.k7:mg  Marketing End Date  Marketing End Date  Strength  Strength  Jama  Jama  Jama  Jama  Jama  |
| povidence X10 (U. Nysponellose 2)  Late (U.NE. 75EV.)  Late (U.NE.     | INBOCAS OF THE PROPERTY OF THE | Size Imprint Code Imprint Code  Marketing Start Date 09/15/2011  Basis of S                                      | no score  Jamm Fl.k7:mg  Marketing End Date  Marketing End Date  Strength  Strength  Jama  Jama  Jama  Jama  Jama  |
| posidone X19 (U. Nyspensellos 2)  Jack (UNIX 258-V)  Jack (UNIX 258-V)  Jack (UNIX 258-V)  Jack (UNIX 258-V)  Product Char  Cole  Shape  Product Char  Cole  Shape  Product Char  Contains  Marketing Cate  No     | INBESTED  RED LETTON TO THE TOTAL TO THE TOT | Size Imprint Code Imprint Code  Marketing Start Date 09/15/2011  Basis of S  memantine by de                     | no score   14mm   FLA7.mg   FLA7.mg   Marketing End Date   Strength   Strengt |
| pavidane K19 (U. Nypromellors 2) atala (U.N. 1822) atala (U.N. 182     | SIBMEST   SIBMES | Size Imprint Code  Marketing Start Date  09/15/2011  Basis of S  nemastise by 6  Score Size                      | no score    Idmm   |
| product K19 (U. Nyspensillos 29 (1) (1) (1) (1) (1) (1) (1) (1) (1) (1)  | INTERNATION  REUTZGOVYZZNY  18 (18 STAPAS (UNB. RISTRYZZZOW)  18 (18 STAPAS (UNB. RISTRYZZZOW)  18 (18 STAPAS (UNB. RISTRYZZOW)  18 STAPA (UNB. RISTRYZZOW)  18 (18 STAPA (UNB. RISTRYZZOW)  18 (18 STAPAS (UNB. RISTRYZZOW)  18  | Size Imprint Code  Marketing Start Date  09/15/2011  Basis of S  nemastise by 6  Score Size                      | mo score  Jame  FLU7mg  FLU7mg  Marketing End Date  trength Strength  Strength  Strength  Strength   |
| powdoon K19 (U. Myspremellose 2)  Late (UNR 258V)  Late (     | INDUCTOR  IN UTSTONYUZN  IN UTSTONYU | Size Imprint Code  Marketing Start Date  09/15/2011  Basis of S  nemastise by 6  Score Size                      | no score    Idmm   |
| powdoon K19 (U. Myspremellose 2)  Late (UNR 258-V)  Late (UNR 258-V)  Late (UNR 258-V)  Late (UNR 258-V)  Product Char  Color  Marketing Cate  NAMENDA  Part 2 of 4  NAMENDA  Product Infor  Route of Admini  Active Ingred  Late (UNR 258-V)  Late (U     | SIBMESTS OF THE PROPERTY OF TH | Size Impriest Code  Marketing Start Date  09/12/2011  Basis of S  FFFIT) memanisies by di  Score Size Impriest C | mo score    Imm   FLL7.mg     FLL7.mg     Marketing End Date     Marketing End Date     Strength   Strength     Strength   I mg     Strength   I mg     TLL34.mg     I mo score     I mm   I mg     I mg   I m |
| powdoon K19 (U. Myspremellose 2)  Late (UNR 258-V)  Late (UNR 258-V)  Late (UNR 258-V)  Late (UNR 258-V)  Product Char  Color  Marketing Cate  NAMENDA  Part 2 of 4  NAMENDA  Product Infor  Route of Admini  Active Ingred  Late (UNR 258-V)  Late (U     | SIBMESTS ON THE STREET NAME OF T | Size Imperiat Code  Marketing Start Date  09/15/2011  Basis of S  1937)  menuation byth  Score Size Imperiat C   | mo score    Imm   FLL7.mg     FLL7.mg     Marketing End Date     Marketing End Date     Strength   Strength     Strength   I mg     Strength   I mg     TLL34.mg     I mo score     I mm   I mg     I mg   I m |
| pavidane K19 (U. Nypromellor 2) particular to the control of the c     | SIBMESTS OF THE PROPERTY OF TH | Size Impriest Code  Marketing Start Date  09/12/2011  Basis of S  FFFIT) memanisies by di  Score Size Impriest C | mo score    Imm   FLL7.mg     FLL7.mg     Marketing End Date     Marketing End Date     Strength   Strength     Strength   I mg     Strength   I mg     TLL34.mg     I mo score     I mm   I mg     I mg   I m |
| systemetics 29 system     | SIBBOSES   SIBOSES   SIBBOSES   SIBOSES   | Size Impriest Code  Marketing Start Date  09/12/2011  Basis of S  FFFIT) memanisies by di  Score Size Impriest C | mo score    Imm   FLL7.mg     FLL7.mg     Marketing End Date     Marketing End Date     Strength   Strength     Strength   I mg     Strength   I mg     TLL34.mg     I mo score     I mm   I mg     I mg   I m |
| pavidence K30 (U. Myspremellene 2) tale (UMP. 25EV.)  polythylene glythylene      | SIBBOSES   SIBOSES   SIBBOSES   SIBOSES   | Size Impriest Code  Marketing Start Date  09/12/2011  Basis of S  FFFIT) memanisies by di  Score Size Impriest C | mo score    Imm   FLL7.mg     FLL7.mg     Marketing End Date     Marketing End Date     Strength   Strength     Strength   I mg     Strength   I mg     TLL34.mg     I mo score     I mm   I mg     I mg   I m |

| Active Ing  | redient/A  | Active Moiety  |                                    |                                     |                         |                           |
|---|--|--|------------------------------------|-------------------------------------|-------------------------|---------------------------|
|   |  | Ingredient Name  |                                    | Basis of S                          | trength                 | Strength                  |
| memantine l   | nydro chlo ri  | de (UNIL JYOWDOUAGO) (memantine - UNILW8O17S   | JF3T)                              | memantine hydr                      | rochloride              | 21 mg                     |
| Inactive I  | ngredient  |  |                                    |                                     |                         |                           |
| sucrose (UNI  |  | Ingredient Name  |                                    |                                     | S                       | trength                   |
| sucrose (UNI<br>povidone K3   |  |  |                                    |                                     |                         |                           |
| hypromellos   | e 2910 (15 !   | MPA.S) (UNII: 36SFW2JZ0W)  |                                    |                                     |                         |                           |
| talc (UNII: 7S  |  |  |                                    |                                     |                         |                           |
| polyethylene  | glycol 400   | (UNII: B697894SGQ)<br>0 (UNII: Q662QK8M3B)   |                                    |                                     |                         |                           |
|   |  | LS) (UNII: 47MLB0FIMV)   |                                    |                                     |                         |                           |
| ammonia (U  | NIL 5138Q19  | FIX)   |                                    |                                     |                         |                           |
| OLEIC ACID  |  |  |                                    |                                     |                         |                           |
| MEDIUM-CH<br>GELATIN (U   |  | YCERIDES (UNII: C9H2L21V7U)  |                                    |                                     |                         |                           |
| ULLATIN(C   | ran zonocz.  | MAY MJ   |                                    |                                     |                         |                           |
| Product C   |  |  |                                    |                                     |                         |                           |
| Color   | WHITE (WH  | ITE TO OFF-WHITE), GREEN (DARK GREEN (OPAQ   | UE))                               |                                     |                         |                           |
| Shape<br>Flavor   | CAPSULE (  | CAPSULE)   |                                    | Size                                |                         | 14mm<br>FL1;21;mg         |
| Contains  |  |  |                                    | Imprii                              | it Code                 | PLI,21;mg                 |
|   |  |  |                                    |                                     |                         |                           |
| Marketi   | ng Infor   | mation   |                                    |                                     |                         |                           |
|   |  | Application Number or Monograph Citation   | Market                             | ting Start Date                     | Marketi                 | ng End Date               |
| NDA   |  | NDA022525  | 09/15/20                           | 11                                  |                         |                           |
| Route of Ad   | ministratio  | ORAL ORAL  |                                    |                                     |                         |                           |
|   |  | Active Moiety Ingredient Name  |                                    | Basis of S                          |                         | C+                        |
|   |  | de (UNIE JYOWDOUA60) (memantine - UNIEW8O17S   |                                    | memantine hydr                      |                         |                           |
| Inactive I  | ngredient  | s  |                                    |                                     |                         |                           |
| sucrose (UNI  |  | Ingredient Name  |                                    |                                     | S                       | trength                   |
| povidone K3   | 0 (UNII: U72   | 59)<br>50WY32X)  |                                    |                                     |                         |                           |
| hypromellos   |  |  |                                    |                                     |                         |                           |
|   |  | MPA.S) (UNII: 36 SFW2JZ0W)   |                                    |                                     |                         |                           |
|   |  |  |                                    |                                     |                         |                           |
| polyethylene  | glycol 400   | (UNII: B697894SGQ)   |                                    |                                     |                         |                           |
| polyethylens<br>polyethylens  | glycol 400<br>glycol 800   |  |                                    |                                     |                         |                           |
| polyethylene<br>polyethylene<br>ethylcellulo<br>ammonia (U  | glycol 400<br>glycol 800<br>ie (100 MPA<br>NIE 5138Q19   | (UNIE 8697894SGQ) 0 (UNIE 9662QK8MBB) .S) (UNIE 47MLB0FIMV) FIX)   |                                    |                                     |                         |                           |
| polyethylene<br>polyethylene<br>ethylcellulos<br>ammonia (U<br>OLEIC ACID   | glycol 400<br>glycol 800<br>se (100 MPA<br>NII: 5138Q19<br>(UNII: 2UMI   | (UNI: B697894SCQ) 0 (UNI: Q662QKBMBB) LS) (UNI: 47MLB0FIMV) FEIX) 1U37CP)  |                                    |                                     |                         |                           |
| polyethylene<br>ethylcellulor<br>ammonia (U<br>OLEIC ACID   | glycol 400<br>glycol 800<br>ie (100 MPA<br>NIE 5138Q19<br>(UNIE 2UMI<br>AIN TRIGL  | (UNE: B6978945CQ)  0 (UNE: Q652QKBMBB)  .S) (UNE: 47MLB0FIMV)  FIX)  9 (UNE: 47MLB0FIMV)  FIX)  9 (UNE: 47MLB0FIMV)  FIX)  9 (UNE: 47MLB0FIMV)   |                                    |                                     |                         |                           |
| polyethylene<br>polyethylene<br>ethylcellulos<br>ammonia (U<br>OLEIC ACID<br>MEDIUM-CH<br>GELATIN (U  | glycol 400<br>glycol 800<br>ie (100 MPA<br>NIE 5138Q 19<br>(UNIE 2UMI<br>AIN TRIGL'<br>NIE 2G86QN  | (LINIE B697894SCQ)  Ø (UNIE Q662QKBMB)  S) (UNIE 479E.B09IMV)  FEX)  JUD7CP)  VECERDES (UNIE C9HQL2IV7U)   |                                    |                                     |                         |                           |
| polyethylene polyethylene ethylcellulor ammonia (U OLEIC ACID MEDIUM-CH GELATIN (U  | glycol 400<br>glycol 800<br>ie (100 MPA<br>NIE 5138Q I9<br>(UNIE 2UMI<br>AIN TRIGLY<br>NIE 2G86QN  | (LINIE B69789-SSCQ)  8 (LINIE GEGENERMER)  SS (CHIEL 4708-BOFINDY)  FEX.  LUDICATY  LUDICATY  LUDICATY  LUDICATY  STÉCS  | Scool                              |                                     | no s                    | core                      |
| polyethylene polyethylene ethylcellulor ammonia (U OLEIC ACID MEDIUM-CH GELATIN (U  Product C Color   | glycol 400 glycol 800 is glycol 800 is (100 MPA NIE 5138Q 19 (UNIE 2UMI AIN TRIGL* NIE 2G86QN  | (LINIE B697894SCQ)  Ø (UNIE Q662QKBMB)  S) (UNIE 479E.B09IMV)  FEX)  JUD7CP)  VECERDES (UNIE C9HQL2IV7U)   | Sco:                               |                                     | no s                    |                           |
| polyethylene polyethylene ethylcellulor ammonia (U OLEIC ACID MEDIUM-CH GELATIN (U  Product C Color Shape Flavor  | glycol 400 glycol 800 is glycol 800 is (100 MPA NIE 5138Q 19 (UNIE 2UMI AIN TRIGL* NIE 2G86QN  | (UNIE B697894SCQ)  (UNIE GESQUANIMB)  (UNIE GESQUANIMB)  (FEN  UNICOP  FEN  UNICOP  FEN  UNICOP  UNICO | Size                               |                                     | 16 m                    | m                         |
| polyethylene polyethylene ethylcellulor ammonia (U OLEIC ACID MEDIUM-CH GELATIN (U  Product C Color Shape Flavor  | glycol 400 glycol 800 is glycol 800 is (100 MPA NIE 5138Q 19 (UNIE 2UMI AIN TRIGL* NIE 2G86QN  | (UNIE B697894SCQ)  (UNIE GESQUANIMB)  (UNIE GESQUANIMB)  (FEN  UNICOP  FEN  UNICOP  FEN  UNICOP  UNICO | Size                               |                                     | 16 m                    | m                         |
| polyethylene polyethylene ethylcelluloi admonia (U OLEIC ACID MEDIUM-CH GELATIN (U  Product C Color Shape Flavor Contains   | glycol 400<br>glycol 800<br>e (100 MPA<br>NIL 5138Q 19<br>(UNIE 2UME<br>AIN TRIGL'<br>NIE 2G86QN<br>CAPS   | (UNE B697894SCQ)  (UNE Q66QNRMBB)  5. (UNE C74B0FIMV)  FEX  UUICTP  VCERIBIS (UNE C916L21V7U)  UUICTP  Stics  UN GAMBS GEREN (OPAQUE))  ULE (CAPSULE)  | Size                               |                                     | 16 m                    | m                         |
| polyethylene polyethylene polyethylene polyethylene ammonia (U OLEIC ACID MEDIUM-CH GELATIN (U  Product C Color Shape Flavor Contains  Marketin Marketing   | glycol 400 glycol 800 e (100 MPA NIL 5138Q19 (UNIE 2UME) AIN TRIGL' NIL 2G86QN CAPS  | (UNE B697894SCQ)  (UNE Q66QNRMBB)  5. (UNE C74B0FIMV)  FEX  UUICTP  VCERIBIS (UNE C916L21V7U)  UUICTP  Stics  UN GAMBS GEREN (OPAQUE))  ULE (CAPSULE)  | Size                               | rint Code                           | 16m<br>FLI;             | m<br>28;mg                |
| polyethylene polyethylene polyethylene ethyleellulos ammonia (U OLEIC ACID MEDIUM-CH GELATIN (U  Product C Color Shape Flavor Contains  Marketin Marketing  | glycol 400 glycol 800 glycol 800 e (100 MPA NIE 51880] i (UNIE 520M) i ( | (LINE B697894SCQ) (CONE QCEQUENTAIN) (CONE QCEQUENTAIN) (FEX) (ULTER OF A CONTROL O | Size                               | rint Code                           | 16 m<br>FLI;            | m<br>28;mg                |
| polyethylene polyethylene polyethylene ethyleellulos ammonia (U OLEIC ACID MEDIUM-CH GELATIN (U  Product C Color Shape Flavor Contains  Marketin Marketing  | glycol 400 glycol 800 glycol 800 e (100 MPA NIE 51880]gl (UNIE 52MB)gl ( | (UNE B697894SCQ)  (UNE Q66QNAMAB)  5 (UNE C74B0FHMY)  FEX  UUUCCP)  FCERIBUS (UNE C396L21V7U)  SSTICS  IN (DARK CREEN (OPAQUE))  ULE (CAPSUE)  THATION  Application Number or Monograph Citation   | Size                               | rint Code                           | 16 m<br>FLI;            | m<br>28;mg                |
| polyethylene polyethylene polyethylene ethylecellulo ammonia (U OLEIC ACID MEDIUM-CH GELATIN (U  Product C Color Shape Flavor Contains  Marketing NDA  Marketing  | e glycol 400 glycol 800 glycol 80 | (UNE B697894SCQ)  (UNE Q64CQNAMAB)  (UNE Q64CQNAMAB)  FEN  UUCCP)  FEN | Size<br>Imp:<br>Market<br>09/15/20 | rint Code rint Code ting Start Date | 16m<br>FLk:<br>Marketin | m<br>28;mg<br>ng End Date |
| polyethylence polyethylence tethyleculation ammonia (U OLEIC ACID MEDIUM-CH GELATIN (U Product C Coolor Shape Flavor Contains Marketin Marketing NDA Marketin Marketing Marketing Marketing Marketing Marketing Marketing Marketing | e glycol 400 glycol 300 glycol 400 glycol 40 | (UNE B697894SCQ)  (UNE Q62QENAMB)  (UNE Q62QENAMB)  (SEQUENT CARBERTON)  FEN  UNITED (UNE CARBERTON)  FEN  UNITED (UNE CARBERTON)  SERIES  SERIES  SERIES  SERIES  MEDIANG CREEN (OPAQUE)  ULE (CAPULE)  ***  ***  ***  ***  ***  ***  ***   | Size<br>Imp:<br>Market<br>09/15/20 | rint Code  ting Start Date          | 16m<br>FLk:<br>Marketin | m<br>28;mg<br>ng End Date |

Labeler - Allergan, Inc. (144796497)

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